K080885 (p5 1/2)

Medacta International

APR 28 2008

Special 510(k) Summary

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Date Prepared: March 28, 2008

DEVICE INFORMATION

Trade/Proprietary Name: Medacta Total Hip Prosthesis System – Line Extension

Common/Classification Name: Hip Joint, metal/polymer/metal semi-constrained cemented prosthesis
21 CFR 888.3350
Class II
Device Product Code: JDI

Predicate Devices:
The Medacta Total Hip Prosthesis – Line Extensions are substantially equivalent to the Medacta Total Hip Prosthesis System cleared under K072857 on Feb. 4, 2008.

Product Modification:
The device modifications to the Medacta Total Hip Prosthesis System which are the subject of this special 510(k) are as follows:

Line Extension to include CoCrMo Femoral ball heads of 22 mm diameter: These CoCrMo femoral ball heads would be used with Quadra® S femoral stems from the Medacta Total Hip Prosthesis System (K072857) and the Ortho Development's Triplus® Acetabular cups and liners.

Line Extension to include CoCrMo Femoral ball heads of 36 mm diameter: These CoCrMo femoral ball heads would be used with Quadra® S femoral stems from the Medacta Total Hip Prosthesis System and the Ortho Development's Triplus® Acetabular cups and liners.

Labeling to allow the use of Medacta Quadra® S stems from Medacta Total Hip Prosthesis system and Medacta CoCrMo Femoral ball heads of sizes 22 and 28 mm with Ortho Development's Pivot Bipolar heads. The Ortho Development's Pivot Bipolar heads were previously cleared under K050966.

Indications for Use:
The Medacta Total Hip Prosthesis System is intended for cementless use in total or partial hip arthroplasty and in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The indications for use for the modified system remain the same as the original 510(k), K072857.

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act.
Risk analysis was conducted on the impact of these changes and appropriate design verification and validation was conducted under the company's design controls.

Conclusion:
The results from design controls and the information provided in this submission support the conclusion that the Medacta Total Hip Prosthesis System – Line Extensions are substantially equivalent to its predicate device, Medacta Total Hip Prosthesis System with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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APR 28 2008

Re: K080885
Trade/Device Name: Medacta Total Hip Prosthesis System – Line Extension
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: March 28, 2008
Received: March 31, 2008

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080885 (pg 1/1)

Device Name: Medacta Total Hip Prosthesis System – Line Extension

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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